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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,267	02/07/2007	Gaetano Giammona	1108.1003	4701

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EXAMINER
BROWE, DAVID

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
11/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/596,267	**Applicant(s)** GIAMMONA ET AL.	
	Examiner DAVID M. BROWE	**Art Unit** 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 November 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,5-15 and 17-19*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1617

Continuation of 11. does NOT place the application in condition for allowance because: Applicants should note that prosecution in this application is closed. Nevertheless, applicants proposed amendments have been entered because they overcome the 35 USC 112 rejection of claims 16-18, of record in the Final Office Action, and, thus, place the application in better condition for appeal. The Examiner maintains the 35 USC 103 rejection of claims 1 and 5-19, of record in the Final Office Action.

Applicant's arguments have been fully considered but they are not found persuasive:

a) Applicant asserts that "Bromberg does not provide for the specific polyaspartamide derivatized polymers presently claimed" and "thus, one skilled in the art would find no motivation to choose a poly-L-aspartic acid among the laundry list of components disclosed in Bromberg and modify it as presently disclosed without the help of impermissible hindsight".
The Examiner, respectfully, cannot agree. The teachings of Giammona et al. provide the disclosure of the specific PHEA polymers claimed and their advantageous use in anionic hydrogels, as discussed in the Final Office Action. The 35 USC 103 rejection of record is based not only on the disclosure of Bromberg et al., but also on the teachings of Blum et al., Giammona et al, and Cavazza. The combination of the disclosure of Bromberg et al. , that anionic hydrogels can be made from irradiation-mediated cross-linking of polyaspartamide; together with the respective teachings of Giammona et al. (the particular polyaspartamide PHEA derivatized with GMA for irradiation-mediated crosslinking to produce anionic hydrogels) and Blum et al. (polymer derivitization with GMA as well as MA with acid comonomers for safe and effective irradiation-mediated cross-linking), outlined in the Final Office Action, render applicants claimed invention obvious within the meaning of 35 USC 103.

b) Applicants assert that "Blum is not analogous to the field of Applicants' endeavor"; "Blum does not afford relevant teachings to the pharmaceutical arts. Nothing in Blum hints to the pharmaceutical arts"; and that, "therefore, one skilled in the art of making drugs would not look to the teachings of Blum, who are limited only to the field of making paintings". Further, Applicant goes on to say that "Blum is not analogous to the field of Applicants invention and does not provide any useful teaching for the person of skill in the pharmaceutical art".
The Examiner, however, cannot agree. Blum makes it explicitly clear that their invention; while potentially applicable to the manufacture of coatings, paints, and surface adhesives; is not limited to such, but rather is intended as a general teaching applicable to any envisaged application that would require cross-linking polymers like (meth)acrylic acid/(meth)acrylate in a clean, safe, and effective manner. (Meth)acrylic acid/(meth)acrylate polymers are routinely employed in the pharmaceutical and medical arts, particularly in drug delivery vehicles; applicant even provides for the incorporation of such polymers in the presently claimed invention (e.g. see claim 10). Blum et al. also disclose how to cross-link such polymers in a clean, safe, and effective manner without the contamination or generation of toxic products. In the pharmaceutical arts, polymers are often crosslinked prior to use in drug-delivery vehicles. For all these reasons, the disclosure of Blum et al. would be of great interest to one of ordinary skill in the pharmaceutical and medical arts. Further, the Examiner maintains, in the present case, Applicant is also seeking a clean, safe, and effective manner to crosslink pharmaceutically acceptable polymers for subsquent use in drug delivery vehicles. Therefore, in the present case, Blum et al. is not only a pertinent reference, it is a key reference the teachings of which disclose the very heart of applicants claimed invention. This position is supported by the following points:
i) Blum et al. disclose a general process for preparing radiation cross-linkable polymers in a clean, safe, and effective manner for use in compositions; the very heart of applicants research work is concerned with producing safe and effective cross-linked polymer hydrogel matrices that can be used to deliver active pharmaceutical agents to patients and animals for medical/veterinary treatment of disease.
ii) Blum et al. disclose a process of preparing (meth)acrylic acid/(meth)acrylate copolymers for irradiation-mediated cross-linking by insertion of GMA and MA groups in the side chains in the presence of acid comonomers; and further disclose using these polymers with suitable agents and excipients in compositions. Preparing polymers for irradiation-mediated cross-linking in this manner, and employing the thus cross-linked polymers in compositions with suitable agents and excipients corresponds with what applicants are claiming as their invention.
iii) (Meth)acrylic acid/(meth)acrylate polymers and copolymers are routinely employed in the pharmaceutical and medical arts, particularly in drug delivery vehicles; applicants provide for the inclusion of acrylic acid polymers in their composition (claim 10); and applicants have previously disclosed a process for preparing PHEA for irradiation-induced cross-linking by the insertion of GMA groups into the side chains, and preparing an anionic hydrogel matrix by irradiation-mediated cross-linking of the modified PHEA polymers.
iv) The Blum et al. Patent is assigned to BASF Coatings AG. Its no surprise, therefore, that Blum et al. would suggest the best mode for the use of their photo-crosslinkable (meth)acrylate copolymers would be in coatings, paints, and surface adhesives. Although Blum et al. do not explicitly state "use this invention in the pharmaceutical arts for the making of anionic hydrogel matrices for drug delivery", one of ordinary skill in the pharmaceutical arts, for the afrementioned reasons, would thus readily recognize and be able to take advantage of the relevant teachings the Blum et al. reference affords to the pharmaceutical arts.

c) Applicants further assert that Cavazza is irrelevant, and only provides for the treatment of chronic inflammatory bowel diseases with lower alkanoyl L-carnitines. The Examiner, however, cannot agree that Cavazza is irrelevant. Since applicants claim a method of treating bowel diseases by administering alkanoyl L-carnitines, its obvious from the disclosure of Cavazza that this aspect of applicants invention is already known and is not patentable.

Therefore, for the aforementioned reasons, the 35 U.S.C. § 103 rejection of claims 1 and 5-19 is hereby maintained..

DMB